K111964

Aalto Scientific, Ltd.

510(k) Notification
Audit® MicroCV™ Urine/Fluids Chemistry Linearity

MAR - 2 2012

510(k) Summary

A. Submitter

Aalto Scientific, Ltd.
1959 Kellogg Ave.
Carlsbad, CA 92008
Telephone: (760) 431-7922
Fax: (760) 431-6824

B. Contact Person

Dessi Lyakov
Regulatory Affairs Manager
Telephone: (760) 431-7922 Ext. 118
E-mail: dlyakov@aaltoscientific.com

C. Date of Summary Preparation

February 29, 2012

D. Device Identification

Product Trade Name:	Audit® MicroCV™ Urine/Fluids Chemistry Linearity
Common Name:	Urine/Fluids Chemistry Linearity
Classification Name:	Assay QC Material
Device Classification:	Class I
Regulation Number:	21 CFR 862.1660
Panel:	75
Product Code:	JJY

Device to Which Substantial Equivalence is Claimed

Product Trade Name:	Audit® MicroCV™ General Chemistry Linearity Set
	Aalto Scientific, Ltd., Carlsbad, CA
	K042318

E. Description of the Device

The Audit® MicroCV™ Urine/Fluids Chemistry Linearity is a aqueous buffer based, lyophilized, two five level sets of QC material, with each level of the first set containing Phosphorous, Urea Nitrogen, Uric Acid.and the second set containing Amylase, Calcium,

Chloride, Creatinine, Glucose, Magnesium, Microalbumin, Microprotein, Potassium, Sodium. It is used to confirm the proper calibration, linear operating range, and reportable range of Phosphorous, Urea Nitrogen, Uric Acid, Amylase, Calcium, Chloride, Creatinine, Glucose, Magnesium, Microalbumin, Microprotein, Potassium, Sodium Level A is near the lower limit level and Level E has concentrations near the upper limit of instruments. Levels B – D are related by linear dilution of Level A and Level E.

F. Statement of Intended Use

The Audit™ MicroCV™ Urine/Fluids Chemistry Linearity Set is assayed quality control material consisting of two sets of five levels of aqueous buffer. Each level of Set 1 contains the following analytes: Phosphorous, Urea Nitrogen, Uric Acid. Each level of Set 2 contains the following analytes: Amylase, Calcium, Glucose, Chloride, Creatinine, Magnesium, Potassium, Sodium, Microprotein, Microalbumin. These five levels of each set demonstrate a linear relationship to each other for their respective analytes, reagents and instruments.

The product is intended for use with quantitative assays on the indicated analyzer specified in the labeling. When used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides. The Audit™ MicroCV™ Urine/Fluids Chemistry Linearity Set is "For In Vitro Diagnostic Use Only".

G. Summary of Performance Data

Stability studies have been performed to determine the reconstituted stability and shelf life for the Audit® MicroCV™ Urine/Fluids Chemistry Linearity Set. All supporting data is retained on file at Aalto Scientific, Ltd. Product claims are as follows:

Reconstituted Stability: Once a vial has been reconstituted, all analytes from Set 1 will be stable for 72 hours when stored tightly capped at 2 - 8° C. All analytes from Set 2 will be stable for 10 days when stored tightly capped at 2 - 8° C.

Shelf Life: One year, when stored unopened at 2 - 8° C.

Note: Real time studies are ongoing to support the shelf life of this product.

H. Technical Characteristics Compared to Predicate Device

Characteristics	Audit® MicroCV™ Urine/Fluids Chemistry Linearity Set (K111964)		Audit™ MicroCV™ General Chemistry Linearity Set (K042318)
Intended Use	The Audit™ MicroCV™ Urine/Fluids Chemistry Linearity Set is assayed quality control material consisting of two sets of five levels of aqueous buffer. Each level of Set 1 contains the following analytes: Phosphorous, Urea Nitrogen, Uric Acid. Each level of Set 2 contains the following analytes: Amylase, Calcium, Glucose, Chloride, Creatinine, Magnesium, Potassium, Sodium, Microprotein, Microalbumin. These five levels of each set demonstrate a linear relationship to each other for their respective analytes, reagents and instruments. The product is intended for use with quantitative assays on the indicated analyzer specified in the labeling. When used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides. The Audit™ MicroCV™ Urine/Fluids Chemistry Linearity Set is "For In Vitro Diagnostic Use Only".		Audit® Micro*CV*™ General Chemistry Linearity Set consists of five levels of human based serum. Each level contains the following analytes: Albumin, Alkaline Phosphatase, ALT, Amylase, AST, Bilirubin (Total and Direct), BUN, Calcium, Chloride, Cholesterol, CO_2, Creatine Kinase, Creatinine, Gamma-GT, LDH, Glucose, HDL Cholesterol, Iron, Lactate, LDL Cholesterol, Lipase, Magnesium, Phosphorus, Potassium, Sodium, Total Protein, Triglycerides and Uric Acid. These five levels demonstrate a linear relationship to each other for their respective analytes, reagents and instruments[1].
Number of Analytes per vial	Set 1 3	Set 2 10	30
Number of levels per set	5		5
Contents	10 x 2 mL		5 x 5 mL
Matrix	Aqueous Based Buffer		Human Based Serum
Type of Analytes	Amylase, Calcium, Glucose, Chloride, Creatinine, Magnesium, Potassium, Sodium, Microprotein, Microalbumin, Phosphorous, Urea Nitrogen Uric Acid,.		Albumin, ALP, ALT, Amylase, AST, Bilirubin (Total and Direct), BUN, Calcium, Chloride, Cholesterol, CO_2, Creatine Kinase, Creatinine, Gamma-GT, Glucose, Iron, HDL Cholesterol, Lactate, LDH, LDL Cholesterol, Lipase, Magnesium, Phosphorus, Potassium, Sodium, Total Protein, Triglycerides and Uric Acid.
Form	Lyophilized		Lyophilized
Storage	2 to 8° C Until expiration date		2 to 8° C Until expiration date
Reconstituted Stability	72 hours at 2 to 8° C for Set 1 10 days at 2 to 8° C for Set 2		1 day at 2 to 8°

I. Conclusions

Based upon the purpose of the device, the descriptions and labeling of the predicate device, the safety and efficacy, and the stability data generated, the product is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Aalto Scientific
c/o Dessi Lyakov
1959 Kellogg Ave.
Carlsbad, CA 92008

MAR - 2 2012

Re: k111964

Trade/Device Name: Audit™ MicroCV Urine/Fluids Chemistry Linearity
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (Assayed and Unassayed)
Regulatory Class: Class I, reserved
Product Code: JJY
Dated: February 2, 2012
Received: February 6, 2012

Dear Ms. Lyakov:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Astho Scientific, Ltd.

510(k) Notification
Audit® MicroCV™ Urine/Fluids Chemistry Linearity

Indications for Use

510(k) Number: K111964

Device Name: Audit® MicroCV™ Urine/Fluids Chemistry Linearity

Indications For Use:

The Audit™ MicroCV™ Urine/Fluids Chemistry Linearity Set is assayed quality control material consisting of two sets of five levels of aqueous buffer. Each level of Set 1 contains the following analytes: Phosphorous, Urea Nitrogen, Uric Acid. Each level of Set 2 contains the following analytes: Amylase, Calcium, Glucose, Chloride, Creatinine, Magnesium, Potassium, Sodium, Microprotein, Microalbumin. These five levels of each set demonstrate a linear relationship to each other for their respective analytes, reagents and instruments.

The product is intended for use with quantitative assays on the indicated analyzer specified in the labeling. When used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides. The Audit™ MicroCV™ Urine/Fluids Chemistry Linearity Set is "For In Vitro Diagnostic Use Only".

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K111964